

## PATENT COOPERATION TREATY

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REC'D 18 JUN 2004

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>PCT 21121Y</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/US03/19013</b>	International filing date (day/month/year) <b>13 June 2003 (13.06.2003)</b>	Priority date (day/month/year) <b>17 June 2002 (17.06.2002)</b>
International Patent Classification (IPC) or national classification and IPC <b>IPC(7): A61K 31/74 and US Cl.: 424/78.04; 514/912, 410, 378</b>		
Applicant <b>MERCK &amp; CO., INC.</b>		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <b>2</b> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <b>0</b> sheets.</p>		

3. This report contains indications relating to the following items:
I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand <b>08 December 2003 (08.12.2003)</b>	Date of completion of this report <b>17 May 2004 (17.05.2004)</b>
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306	Authorized officer Vickie Kim Telephone No. 571-272-1600 <i>J. Roberts for</i>

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

- the international application as originally filed.
- the description:  
pages 1-32 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- the claims:  
pages 33-47, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- the drawings:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

- the description, pages NONE
- the claims, Nos. NONE
- the drawings, sheets/fig NONE

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-11</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-11</u>	NO
Industrial Applicability (IA)	Claims <u>1-11</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-11 lack novelty under PCT Article 33(2)-(3) as being anticipated by Garcia et al(US2001/0047025). The invention of US'025 relates to the use of potent potassium channel blockers or a formulation thereof in the treatment of glaucoma or other conditions related to elevated intraocular pressure(e.g. macular edema or macular degeneration) in the eye. US'025 also teaches that the potassium channel blocker such as paxilline and its derivatives, see paragraph 133-134. US'025 further teaches a combination of the said potassium channel blocker and other secondary active agent such as beta adrenergic blocking agent, see column 3, paragraph 36-38. US'025 teaches topical ophthalmic application and a pharmaceutically acceptable carrier such as xanthan gum, see column 7, paragraph 113 and 126. All the critical elements required by the instant claims are taught by the cited reference and the claims are not novel over the prior art of the record.

Claims 1-11 meet the criteria set out in PCT Article 33(4), and thus the claimed invention has industrial applicability because the subject matter claimed can be made or used in industry.

## PATENT COOPERATION TREATY

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## NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No.	Applicant's or agent's file reference	Date of informal communication (day/month/year)
PCT/US03/19013	PCT 21121Y	17 May 2004 (17.05.2004)
Applicant MERCK & CO., INC.		

<u>Communication</u>	<u>Participants</u>	<input checked="" type="checkbox"/> Identity checked	<input type="checkbox"/> authorization checked	<input type="checkbox"/> personally known
<input checked="" type="checkbox"/> by telephone	<input checked="" type="checkbox"/> Applicant: MERCK & CO., INC.			
<input type="checkbox"/> personal	<input checked="" type="checkbox"/> Agent: Sylvia A. Ayler			
	<input checked="" type="checkbox"/> Examiner(s): Vickie Kim			

Summary of communication:

Preparation of IPER(409, International Preliminary Examination Report) by skipping 408(written opinion) was authorized to expedite the prosecution.

<input type="checkbox"/> An extension of time limit is granted (Form PCT/IPEA/427).
<input checked="" type="checkbox"/> A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424: 416 & NO 9

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Vickie Kim <i>J. Roberts for</i>
Facsimile No. (703) 872-9306	Telephone No. 571-272-1600

Form PCT/IPEA/428 (July 1992)